Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13005

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

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Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 85817
13005

A. Patient information

1. Patient identifier [redacted] In confidence
2. Age at time of event: 21 or Date of birth: [redacted]
3. Sex: ☐ female ☑ male
4. Weight: 205 lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☑ required intervention to prevent permanent impairment/damage
   - ☐ other: ____
3. Date of event (mo/day/yr)
4. Date of this report (mo/day/yr): 6/16/98
5. Describe event or problem

PATIENT STARTED TAKING "RIPPED FUEL" IN EARLY MAY 98 ON THE ADVISE OF A TRAINER FOR INCREASING MUSCLE TONE AND REDUCING BODY FAT. THE FOLLOWING SYMPTOMS WERE NOTED:
- TOTAL PERSONALITY CHANGE
- EASILY ANGERED, WOULD GO INTO A RAGE
- NERVEOUSNESS
- WEIGHT LOSS, MISSED MEALS OFTEN
- INABILITY TO REASON, LYING
- GENERALLY "STRUNG OUT"
- LOSS OF MEMORY
- CYCLES OF EUPHORIA / DEPRESSION
- LONG PERIODS WITHOUT SLEEP (24 HOURS OR GREATER)
- LOSS OF MEMORY DURING THE TIME HE WAS ON RIPPED FUEL

6. Relevant tests/laboratory data, including dates

BLOOD TESTS WERE PERFORMED AT THE REQUEST OF AN M.D. TO CHECK ON ELECTROLYTE INBALANCES. DO NOT KNOW RESULTS BECAUSE OF DOCTOR/PATIENT CONFIDENTIALITY.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NONE

REC'D.
JUL 01 1998
MEDWATCH CTU

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 RIPPED FUEL (MA HUANG 334 mg/CAP + GUARANA EXTRACT 910 mg/CAP) TWINLAB
2. Dose, frequency & route used
   #1 2 CAPS 3X/DAY BEFORE MEALS
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 2-3 WEEKS
4. Diagnosis for use (indication)
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1 NK
7. Exp. date (if known)
   #1 NK
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

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D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ____
5. Expiration date (mo/day/yr)
6. model # ____ catalog # ____ serial # ____ lot # ____ other # ____
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted]
2. Health professional? ☐ yes ☑ no
3. Occupation: ENGINEER
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

000002

Adverse Reaction Information Form A

Complaint Number: _____ Investigator: Jose R. Rodriguez

Consumer Information

Date of Report: 09/22/98 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 21

Race: ☑1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 6/16/98
Previous Reaction to Product Type: ☐Yes ☐No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Total personality change, nervousness, weight loss, loss of memory
How long did the symptoms last? For 3 weeks after stopped taking
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.).

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: None

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☑Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☐MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☒Other (specify) Psychiatrist

What medical tests were performed and what were the results? See medical record

What was the medical diagnosis? Bipolar disorder
What treatment(s) was given (e.g., drugs, other)? Medicine except to stop taking the product.

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

Product Category

1. Adverse reaction to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☐**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☒**Other** (traditional food) Caffeine

Other Product Problems

2. ☐Foreign Object (specify): _____
3. ☐Other (specify): _____

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Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
Ripped Fuel 2 caps 3 times a day. Took product for approximately two weeks following the recommendation of a trainer

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

Ma Huang Extract

Guarana Extract (22% caffeine)

L - Carnitine

Chromium

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☑Other Caffeine
☐Unknown

☐Color Additive (please specify) _____

Product Label Available: ☑Yes ☐No ☐Unknown Product Sample Available: ☐Yes ☑No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☑No

Life-Threatening: ☐Yes ☑No

Hospitalization: ☐Yes ☑No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☑No

Did the adverse reaction result in a congenital anomaly: ☐Yes ☑No

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

MEMORANDUM

Date: September 22, 1998

From: Investigator, J.R.Rodriguez

Subject: Assignment ORL #080305

To: Supervisor, T.G. Forrest

On 8/7/98 I telephoned Mr. [redacted] as follow up to his adverse vent/product problem reported by him to Medwatch.

Mr. [redacted] stated that the person affected by Ripped Fuel was his son who started showing signs of total personality change, in which he easily angered and showed symptoms such as: nervousness, weight loss, inability to reason, loss of memory, cycles of euphoria and depression. He added that his son started to take Ripped Fuel somewhere early in May at the advice of a trainer to increase muscle tone and reduce body fat. A physician was visited at the [redacted] for treatment.

Mr. [redacted] also informed that his son does not tolerate caffeine. He works for a pest control firm and spends most of his time in the street. Mr [redacted] provided me with the telephone number of his son [redacted]

Upon calling him, he stated that he purchased the product at a [redacted] store located at the [redacted] following the recommendations of a trainer. He stated that he was taking six capsules per day, two in the morning, two at around noon, and two others at night. He mentioned that he visited a psychiatrist at the [redacted] for treatment. I asked to meet with him to get a medical release form signed. Mr. [redacted] asks what is he going to get by complaining to FDA. I told him that we will investigate if there are any more complaints against the product, beside getting a diagnosis from his doctor. Mr. [redacted] states that he does not want to provide more information to me by telephone and says that he will call me on Aug. 10, to set up a meeting because he was going out for the weekend.

Since no calls were received on 8/10/98 I telephoned him on the same date, but received no answer.

On 8/12/98 I again telephoned him and he stated that he was busy preparing to go out and could not talk to me at this time.

On 8/13/98 I again telephoned his home, but no response was obtained.

On August 20, 1998 Mr. [redacted] left a message to call him back to make an appointment. After talking to him an appointment was made for September 8, 1998.

On 9/8/98 I visited Mr. [redacted] at his parents home located at [redacted] however he was not there yet. His mother stated that [redacted] could not handle caffeine since he was eight years old, and his food intake was limited to product that were caffeine free. She added that caffeine will make him hyperactive. Mrs. [redacted] stated that at the present time [redacted] is approximately 95% normal again. She added that his son became hostile with friends and relatives, he had problems trying to sleep and appeared to be suffering from sleep depravation, and was not eating enough. He used to spend up to three hours a day at a gym exercising.

When Mr. [redacted] arrived he stated that he did read the label of the product and noticed that it had caffeine in it, but was unaware that he will have an adverse reaction to the Ripped Fuel since it was recommended to him by a trainer to increase the size of his muscles and reduce fat. He added that he is not aware that he has any allergies to other products. The side effects that he experience after taken the product two capsules three times a day, lasted for approximately three weeks after he stop taking the product. Mr. [redacted] provided me with the empty bottle of the product.

Mr. [redacted] stated that on 6/18/98 he visited [redacted] because of the symptoms he was experiencing that included a total personality change. He added that he was diagnosed as having a bipolar disorder (manic depression). Mr. [redacted] also made several inquiries about a law suit against the manufacturer of the product. I suggested him to contact a lawyer if he wanted to pursue any legal action against the firm. Mr. [redacted] signed an Authorization for Medical Records Release for me to obtain a copy of his medical records.

On 9/8/98 I visited [redacted] identified myself and talked to the Business Manager Ms. [redacted] who stated that she needed the approval of the physician to provided the medical services to Mr. [redacted] to release the records. She added that particular physician was not there and

would be coming in the following day. Once the physician release the medical record a copy will be made and mailed to FDA.

A copy of the psychiatric record for Mr. [redacted] was received on Sept. 15, 1998.